

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

PATENT SPECIFICATION

(11) 1 294 808

1 294 808

DRAWINGS ATTACHED



(21) Application No. 38979/71 (22) Filed 19 Aug. 1971

(45) Complete Specification published 1 Nov. 1972

(51) International Classification A61M 16/00

(52) Index at acceptance

AST 200 303 305 313 613 617
B1R 1B

G3R 1A 36A2 36F3 36H1 61 68 70 8R

(72) Inventors GEORGE EDWARD SMYTHE
and WILLIAM FREDERICK COX

(54) TEMPERATURE-CONTROLLED GAS HUMIDIFIER FOR A MEDICAL VENTILATOR

(71) We, PHILIPS ELECTRONIC AND ASSOCIATED INDUSTRIES LIMITED, of Abacus House, 33 Gutter Lane, London, E.C.2, a British Company, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

5 The present invention relates to a gas humidifier of the so-called "gas-over-hot-water" type for humidifying respiratory gas fed from a medical ventilator to a patient and more particularly to temperature controlling 10 means for regulating the temperature of the water.

15 Humidifiers are used during ventilation of a patient in order to add water vapour to the respiratory gas passed to a patient in each inspiration period in order to replace the loss of water from the patient during 20 exhalation. In the "gas-over-hot-water" type of humidifier, the respiratory gas is passed over the surface of a quantity of water 25 in a vaporisation chamber in its passage from a gas supply source to the patient. The water is heated in order to increase 30 the evaporation rate (so requiring a smaller free surface of water) and to warm the gas passed to the patient.

35 It is customary in such humidifiers to heat the water to a predetermined temperature by means of an immersion heater controlled by a thermostat which senses the water temperature in the vaporisation chamber. The known method, however, has certain disadvantages, the main one being that temperature of the gas received by the patient can vary over very wide limits with variation 40 of gas flow rate, ambient temperature, water temperature, and on the length of the hose line between the humidifier and the patient. To cater for these variations, the humidifier water temperature is set on the safely low

side to ensure that the gas temperature at the Y-piece of the face mask or respiratory tube does not exceed normal body temperature. This safety procedure results in the temperature of the gas at the Y-piece being lower than the desired body temperature with the result that the patient uses heat energy to raise the temperature of the gas. This, of course, is undesirable since any person being ventilated is generally in a low state of health and any wasteful use of his energy should be avoided.

45 50 55 The object of the present invention is to overcome the above disadvantage.

According to the present invention there is provided a gas humidifier for humidifying respiratory gas fed from a medical ventilator to a patient, including a "gas-over-hot-water" vaporisation chamber, means for heating water contained in the chamber, a respiratory gas supply line arranged for feeding humidified respiratory gas from the humidifier to a patient, an electrical temperature-sensing element located at or adjacent the patient end of the supply line for sensing the temperature of humidified respiratory gas immediately before the gas is passed to the patient during an inspiratory period of the ventilator, and controlling means for controlling the operation of the water heating means in dependence upon the temperature sensed by the temperature sensing element whereby the said temperature is maintained at a predetermined level.

60 65 70 75 80 By sensing the temperature of the gas at a point as near as practical to the patient, it is readily possible to control the water temperature so as to maintain the temperature at this point at a predetermined level, e.g. 37°C.

85 Two flexible hoses are generally used for feeding respiratory gas respectively to and from a patient and these are fixed at the patient ends thereof to two respective

branches of a 3-branch pipe assembly, the third branch being connected to or forming the common inspiration/expiration part of the mouthpiece or respiratory tube. Although 5 nowadays not always in the form of a "Y", this assembly is nevertheless referred to in the art as the Y-piece. Since the Y-piece is a rigid structure, the sensing element is preferably located in the Y-piece rather than 10 in the flexible inspiratory hose.

Preferably, the sensing element is a thermistor.

In a preferred embodiment of the humidifier according to the invention various fail-safe devices are incorporated which ensure that in the event of a fault, for example disconnection of the sensor leads or of dangerous overheating of the water, the heating element is automatically disconnected. 20

The various advantages of the present invention will be apparent from the following description of exemplary embodiments thereof, taken in conjunction with the accompanying drawings, of which,

Figure 1 is a block functional drawing of a humidifier according to the invention.

Figure 2 is a schematic circuit diagram showing the temperature control principle,

Figure 3 is a detailed circuit drawing of the circuit of Figure 1 and including fault detection circuitry, and

Figure 4 is a detailed circuit drawing of the alarm and safety cut-out circuitry.

Referring now to Figure 1 of the drawings, which shows a functional block diagram, a humidifying chamber 1 has an inlet 2 and an outlet 3 for respiratory gas. The chamber contains water 4 heated by an electric heating element 5. In operation,

respiratory gas is passed from inlet 2 over the hot water in the chamber and thence to outlet 3 having picked up water vapour from the water surface. The humidified respiratory gas is then fed via a flexible hoseline 6, typically of about one metre length, to the inspiratory gas inlet 7 of Y-piece 8 and thence to a face-mask or endotracheal tube via connection 9. The ex-

piratory gas path is via connections 9 and 10 of the Y-piece and will not be described further since it is not relevant to an understanding of the present invention. All that need be said is that the Y-piece is located

as close to the patient as possible so that the exhaled gas retained, at the end of an expiration period, between the connection 9 and the patient's lungs is a minimum; since this "used" gas is inhaled again at the next inspiration period. Thus the smaller the volume of the gas path common to the inspiration and expiration paths, the more fresh respiratory gas is fed to the patient in each respiratory cycle.

65 A temperature sensor 11 is located in the

stub end of the Y-piece 8 so as to sense the temperature of the inhaled gas at a convenient point close to the patient. The sensor, formed by a negative temperature coefficient resistor such as a thermistor, is connected electrically to a comparison device 12 via a plug and socket connection 13. The socket is located on a front panel of the humidifying unit, as is the inspiratory hoseline connection, to enable the facemask and hoseline to be removed from the humidifier for sterilizing, etc.

A temperature-setting control device 14, comprising a temperature-calibrated potentiometer also mounted on the control panel, is connected to a second input of the comparison device 12. The output of comparison device 12 is fed to a switching control unit 15 which controls a heater power supply switching arrangement 16 comprising a triac arranged in the supply path from a heater power supply 17 to the heater 5.

In operation, the comparison device 12 compares the sensor and temperature-setting signals and gives an output if the temperature sensed by sensor 11 is lower than the temperature represented by the setting of setting control 14. This output causes the switching control to feed triggering pulses to the gate electrode of triac 16 at the beginning, or "zero crossing", of each half cycle of the a.c. supply 17 and, hence, to supply heating current to the heating element 5. The water temperature is therefore raised and this increases the temperature of the gas passed through the humidifying chamber 1.

When the gas temperature at the Y-piece equals the predetermined temperature (e.g. 37°C) set by adjustable control 14, the inputs to the comparison device 12 become equal and the latter no longer provides an output signal. Switching control 15 therefore no longer provides triggering pulses to triac 16 and, hence, the current supply to heating element 5 is switched off.

In this way, the gas temperature at the Y-piece is maintained substantially equal to the predetermined temperature set on control 14. The comparison device 12 is conveniently a differential amplifier.

In order to protect the patient, several safety features are incorporated which switch off the heating element, and so prevent overheating of the inspired gas, if a fault occurs in the temperature control circuitry. The most likely faults are concerned with the temperature sensor and the leads therefrom; i.e. the leads may become short-circuited or open-circuited, or the plug and socket connection 13 may become inadvertently disconnected. Any of these conditions is detected by a fault-detector 18 connected to the sensor leads at point 19. If a fault is detected, detector 18 inhibits the

switching control 15 via lead 21 and, hence, prevents operation of the heating element.

If, by any chance, the water still becomes overheated, this is sensed by a water temperature detector 22, such as a bimetallic switch and this causes operation of the fault detector 18.

Having described the operational function of the various circuit elements involved, the circuit operation of the temperature control system will now be described with reference to Figure 2 of the drawings.

A 24 volt alternating current is applied to inputs *a* and *b*. Resistor R1 and Zener diode V1 produce positive half cycles of the a.c. having a +12V peak at the junction of resistors R1 and R2. A resistance bridge network is formed by resistors R2 to R9, the balance arm junctions of this bridge being connected to input terminals 2 and 3 of an integrated circuit block IC. Resistor R4 is a potentiometer which forms the temperature setting control 14 of Figure 1. R7 is a negative temperature coefficient resistor such as a thermistor and forms the temperature sensing device 11 of Figure 1. The integrated circuit IC includes a differential amplifier DA which compares the voltages appearing at the IC inputs 2 and 3. This forms the comparison device 12 of Figure 1. The output of this amplifier controls a switching circuit such that short output pulses are given at terminal 11 at every zero-crossing of the a.c. supply voltage when the input at terminal 3 of the IC is more positive than the input at terminal 2. Such integrated circuit blocks are very well known and are used for providing triggering current pulses to switch on triacs at the point of zero current crossing. The particular IC used in the practical embodiment, described herein-after with respect to Figure 3, is a Fairchild Semiconductor's μ A742 Zero Crossing AC Trigger Trigac and the terminals shown in the Figures are the same as the pin numbers of the TRIGAC. The internal circuitry of the IC is not relevant to the present description—all that is required from the IC is that triggering pulses are produced when terminal 3 is more positive than terminal 2—but a full circuit and description is given in "Applications of the μ A742 TRIGAC" published by Fairchild Semiconductor. This particular IC uses a change in charge on an external capacitor to provide the triggering pulses at output 11 and this capacitor is shown as C1 in Figure 2.

Triggering current output pulses appearing at terminal 11 of the IC fire a triac Tr at every zero-crossing of the a.c. supply voltage at terminals *a* and *b* and cause the triac to conduct. The synchronism of these triggering pulses with the zero-crossing is achieved via a synchronising input to terminal 10 of the IC derived from the a.c. supply. Triac Tr is in series with a bimetallic switch Th (22 of Figure 1) and a heating element Htr (forming heater 5 of Figure 1) across the a.c. supply. Thus a.c. current is passed to the heating element when the triac is triggered by the pulses from the IC.

If the temperature of the gas at the Y-piece (Figure 1) is the same as that set by temperature-calibrated potentiometer R4, the amplitudes of the positive half pulses appearing at input terminals 2 and 3 of the IC are the same. Under this condition, therefore, triac Tr is not fired and no current is fed to heater Htr. If the Y-piece temperature now falls, the resistance of thermistor R7 increases and the amplitude of the pulses at terminal 2 therefore decreases. The pulses at terminal 3 are now more positive-going than those at terminal 2 and under this condition, as previously explained, the IC produces triggering pulses at its output 11 and current is passed to the heater via triac Tr. This causes the temperature of the humidifier water to be increased and this in turn increases the temperature of the respiratory gas at the Y-piece and, hence, reduces the resistance of thermistor R7. When this latter temperature is again equal to the predetermined temperature set by potentiometer R4, the signals at terminals 2 and 3 are again equal and the triac is no longer fed at its gating electrode with triggering pulses. The heater Htr is therefore disconnected.

In the practical embodiment, various safety features are incorporated and these will now be described with reference to Figure 3 and Figure 4 of the drawings. In Figures 2 and 3, the same circuit elements are given the same designations.

Referring now to Figure 3, the left hand arms of the bridge (resistors R2 to R6) are fed with current via the emitter-collector path of a transistor V4 and the right hand arms of the bridge (resistors R7 to R9) are fed with current via the emitter-base path of V4. Transistor V2 is normally cut off because the emitter-collector voltage (about 0.1 to 0.2V) of conducting transistor V4 is too low for current to pass via diode V3 and the emitter-base path of V2. Under this condition, therefore, the circuit functions as described with reference to Figure 1, the positive peak potential at input 2 of the IC being generally in the range 6 to 7 volts.

In the practical embodiment, resistors R7, R8 and R9 are encapsulated in a block and located at the Y-piece with the thermistor R7 projecting into the Y-piece as shown in Figure 1. Thus three leads are required from this block to the control equipment, each lead being provided with a plug and socket connection 13. If any or all three of these leads become disconnected (e.g.

130

130

by wear or by accidental disconnection of the plug) the peak potential appearing at pin 2 of the IC and lead *c* rises above the value corresponding to the maximum safe 5 gas temperature e.g. 42°C. If the connections to R7 or R9 are broken, V4 stops conducting and V2 conducts and the voltage of pin 2 of the IC is raised towards 12v through R16 and the collector of V2. If 10 the lead to the junction of R7/R8 is broken the voltage of pin 2 of IC is raised towards 21v through R11. These high level peaks (referred to hereinafter as the high level voltage) cause the alarm circuit, shown and 15 described later with reference to Figure 4, to operate and give an audible and/or visual alarm. They also operate discretely on the IC and stop this supplying triggering pulses to the triac.

20 The other fault that may occur in the leads is a short circuit between them. If this occurs, the resistance values are so arranged that, irrespective of whether any two or all three leads become short-circuited, 25 the peak voltages appearing at terminal 3 of the IC have maximum value of about three volts. This value is referred to as the low voltage level hereinafter and this also cause operation of the alarm. Thus, in the 30 event of any fault on the leads, the voltage level appearing on lead *c* either doubles (high voltage level) or halves (low voltage level).

35 The other addition to Figure 1 shown in Figure 3 is a further transistor circuit comprising transistor V5, diodes V6 and V7, and resistors R13, R14 and R15. This circuit senses opening of the bimetallic switch 40 Th caused by overheating of the water in the humidifier. Normally with the bimetallic switch contact closed, the base-emitter circuit of V5 is short circuited thereby and this transistor is thus normally in the cut-off state. If the bimetallic switch contact 45 opens, however, V5 conducts supply current via the heater Htr and diode V7 to lead *e*. This also causes an alarm to be given, as will be described later with reference to Figure 4.

50 In the practical embodiment, all the elements of Figure 3 shown within the chain outline except R4 (which is panel-mounted) are mounted on a printed circuit board (p.c.b.), and it will be seen that the triggering lead from output 11 of the IC to the 55 gating electrode of triac Tr is taken via lead *g* out of the printed circuit board. It will be seen from Figure 4 that this lead *g* returns as lead *h* to the triac. The reason for this is that the whole of Figure 4 is constructed on a separate printed circuit board, the removal of which will thus disconnect the triggering pulse path to the triac. Thus, 60 if either p.c.b. is removed, the heater Htr 65 cannot be supplied with heater current;

thereby providing a further feature which prevents overheating of the humidifier water in the event of a fault.

Resistors R5 and R8 (Figures 1 and 2) are made preset variable resistors. These are preset during calibration of the temperature control adjustment. In the practical embodiment, the following components were used for Figure 3.

R1	3.3 Kohms	R10	120 ohms	75
R2	6.8 Kohms	R11	270 Kohms	
R3	2.7 Kohms	R12	1.2 Kohms	
R4	2.0 Kohms	R13	1.0 Kohms	
R5	2.2 Kohms	R14	150 Kohms	70
R6	6.8 Kohms	R15	4.7 Kohms	
R8	5.0 Kohms			80
R9	3.9 Kohms			
			R7 Mullard VA3406	
V1	Mullard	BZY 88	C12	
V2	Mullard	BCY 71		85
V3	Mullard	BAX 17		
V4	Mullard	BCY 71		
V5	Mullard	BCY 71		
Tr	Mullard	BGX 94/100		
C1	0.47 μ F			
C2	0.47 μ F			90
IC	Fairchild Semiconductor TRIGAC μ A742			

Capacitor C2, between terminals 1 and 4 of the IC, is used in the latter as a memory storage for maintaining the control condition during negative line half cycles (when the circuit is, in effect, idling). The stored energy forces the differential amplifier DA to assume the previously held state at the beginning of each positive half cycle. The 100 IC produces triggering output pulses when the voltage at terminal 3 is positive to that at terminal 2 by a voltage of about 3 millivolts. The voltage at the junction of R9 and R10 is fed to terminal 7 of the IC to 105 feed a clamping circuit in the IC which has the effect of producing a snap action in the comparator.

The alarm circuit will now be described with reference to Figure 4 of the drawings, 110 the connecting leads between Figures 3 and 4 being given the same reference in each drawing.

The circuit is powered from the 24v a.c. supply at terminals *a* and *b*, this being rectified and stabilised to provide a +20V d.c. by means of resistor R21, rectifying diode V21, capacitor C11, resistor R22, and Zener diode V22.

Lead *c*, which feeds a normal level voltage of 6-7 volts, as previously described, feeds two long-tailed pairs, comprising transistors V23, V25 and V26, V28, via isolating resistors R23 and R24 respectively. The common emitter resistors for these long-tailed pairs are R25 and R31 respectively. A voltage divider formed by resistors R27

to R30 provides base bias potentials for V25 and V28. During normal operation the voltage on lead *c* is between the base bias potentials of V25 and V28, transistors V25 and V28 are conducting and V23 and V28 are non-conducting. If a high level voltage is received over lead *c*, V23 conducts and feeds current to the base of transistor V29, which is normally cut off. If a low level voltage appears on lead *c*, V28 conducts and, again, feeds current to the base of V29. Thus, in the event of a fault condition on the thermistor leads, as previously described, either a high or low level voltage signal on lead *c* causes V29 to conduct. The resultant current pulses flowing through the emitter-collector path of V29 and resistor R36 are applied to the base of V31 of a conventional flip-flop circuit comprising resistors R34 to R39 and transistors V31 and V32. In the normal (non-alarm) state, V32 is conducting and V31 is non-conducting. This condition is ensured on switching on the equipment by condenser C22. Under alarm conditions the current applied to the base of V31 causes the flip-flop to change state; V31 then conducting and V32 becoming non-conducting. The function of this flip-flop is to memorise a fault and prevent the heater being re-energised until manual operation of a push button switch.

If the bimetallic switch Th (Figure 3) opens, V5 feeds current over lead *e* as previously described, and hence, to the base of V31. Thus this alarm condition also causes the flip-flop to change state.

With the flip-flop in the normal (non-alarm) state with V32 conducting, collector current is drawn for this transistor largely via resistor R41 and diode V33 in parallel with resistor R44 and diode V36. Since the collector-emitter potential of V32 is very low in the conducting state, no current flows via diode V34 or via diode V37. Thus no current flows to the bases of transistors V35 and V38. These transistors are therefore normally cut-off.

Under alarm conditions, when V32 is non-conducting, the potential at the collector of V32 is substantially at +20V and diodes V33 and V36 cease to conduct. Current can now flow to the bases of V35 and V38 causing these transistors to conduct. The collector current of V35 lights an alarm lamp LP. Due to the fact that V38 is conducting, the potential on lead *f* is virtually that of supply terminal *b* with the result that capacitor C1 (Figures 2 and 3) is shunted and cannot charge. This prevents any trigger pulses appearing at terminal 11 of the IC and triac Tr can no longer conduct current to heater Htr.

When the fault is cleared the flip-flop is reset by momentary operation of a push-

button S1. This applies current from the +20V supply line to the base of V32, thereby resetting the flip-flop to the non-alarm state. It can thus be seen that in the event of any fault or misoperation of the control circuitry, the heater current is disconnected and remains disconnected until the fault has been cured and S1 pressed. Therefore, the temperature of the humidified inspiratory gas fed to the patient cannot exceed a safe level.

In a practical embodiment of a humidifier, all parts of the gas circuit are housed in such a way that they can be removed "en bloc" for sterilizing in an autoclave. The heater normally passes about 7 amperes and its sudden disconnection from the circuit by removal of the gas circuit components would produce a large spark at the breaking electrical contacts. A further feature of the embodiment is the provision of an electrical contact switch S2 which closes, on removal of the gas circuit, before the heater connections break. This switch short circuits leads *c* and *d*, thus putting a high voltage level signal (+12V) on lead *c*. The alarm circuit therefore operates in the manner previously described and the heater circuit is therefore disconnected before the heater contacts break.

The circuit component for Figure 4 were, in a practical embodiment:—

R21	22 ohms	R33	6.8 Kohms	
R22	100 ohms	R34	3.3 Kohms	100
R23	100 Kohms	R35	12 Kohms	
R24	100 Kohms	R36	12 Kohms	
R25	47 Kohms	R37	3.3 Kohms	
R26	100 Kohms	R38	12 Kohms	
R27	1.2 Kohms	R39	12 Kohms	
R28	5.6 Kohms	R40	22 Kohms	105
R29	5.6 Kohms	R41	2.2 Kohms	
R30	2.2 Kohms	R42	22 Kohms	
R31	47 Kohms	R43	150 ohms	
R32	2.2 Kohms	R44	47 Kohms	
C21			400 μ F	
C22			1 μ F	110
V21	Mullard	BYX36—150		
V22	"	BZY88—C20		
V23	"	BC107		
V24	"	BAX17		
V25	"	BC107		
V26	"	BC107		
V27	"	BAX17		
V28	"	BC107		
V29	"	BCY71		120
V30	"	BAX17		
V31	"	BC107		
V32	"	BC107		
V33	"	BAX17		
V34	"	BAX17		
V35	"	BC107		125
V36	"	BAX17		
V37	"	BAX17		
V38	"	BC107		

WHAT WE CLAIM IS:—

1. A gas humidifier for humidifying respiratory gas fed from a medical ventilator to a patient, including a "gas-over-hot-water" vaporisation chamber, means for heating water contained in the chamber, a respiratory gas supply line arranged for feeding humidified respiratory gas from the humidifier to a patient, an electrical temperature-sensing element located at or adjacent the patient end of the supply line for sensing the temperature of humidified respiratory gas immediately before the gas is passed to the patient during an inspiratory period of the ventilator, and controlling means for controlling the operation of the water heating means in dependence upon the temperature sensed by the temperature sensing element whereby the said temperature is maintained at a predetermined level.

2. A gas humidifier according to Claim 1 wherein the temperature-sensing element is a negative temperature coefficient resistor arranged in one branch of a resistance bridge the other branch of which includes a potentiometer the setting of which determines the predetermined temperature, the bridge being balanced when the gas temperature equals the predetermined temperature, the outputs from the arm junctions of the two branches being connected to inputs of a comparison device arranged to detect a bridge unbalance caused by the gas temperature being lower than the predetermined temperature, and to provide an output signal in that event, the humidifier including switching means for controlling the operation of the said heating means in dependence upon the said output signal.

3. A gas humidifier according to Claim 2 wherein the switching means includes a triac in series with the heating element and a pulse generator arranged to supply trigger pulses to the gating electrode of the triac to render the triac conducting in the event of said unbalance of the bridge.

4. A gas humidifier according to any previous Claim including means for preventing operation of the heating element if connecting leads to the temperature-sensing element become short-circuited or disconnected.

5. A gas humidifier according to any previous Claim including a thermal switch in the vaporisation chamber which operates at a given temperature to prevent operation of the heating element in the event of the water overheating to reach the given temperature.

6. A gas humidifier substantially as hereinbefore described with reference to Figure 1 of the accompanying drawings.

7. A gas humidifier substantially as hereinbefore defined with reference to Figures 1 to 4 of the accompanying drawings.

C. A. CLARK,
Chartered Patent Agent,
Century House,
Shaftesbury Avenue,
London, W.C.2.
Agent for the Applicants.

Printed for Her Majesty's Stationery Office by Burgess & Son (Abingdon), Ltd.—1972
Published at The Patent Office, 25 Southampton Buildings, London, WC2A 1AY
from which copies may be obtained

1294808

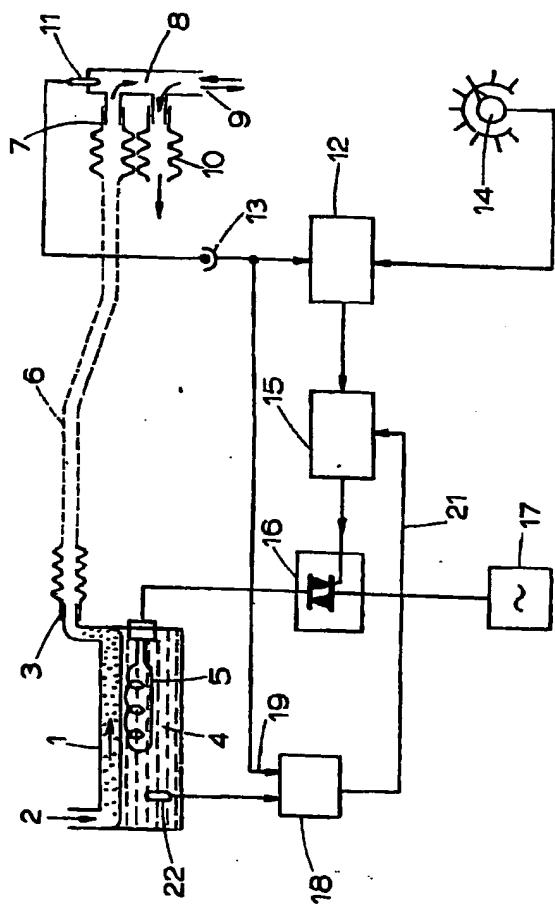
COMPLETE SPECIFICATION

4 SHEETS

*This drawing is a reproduction of
the Original on a reduced scale*

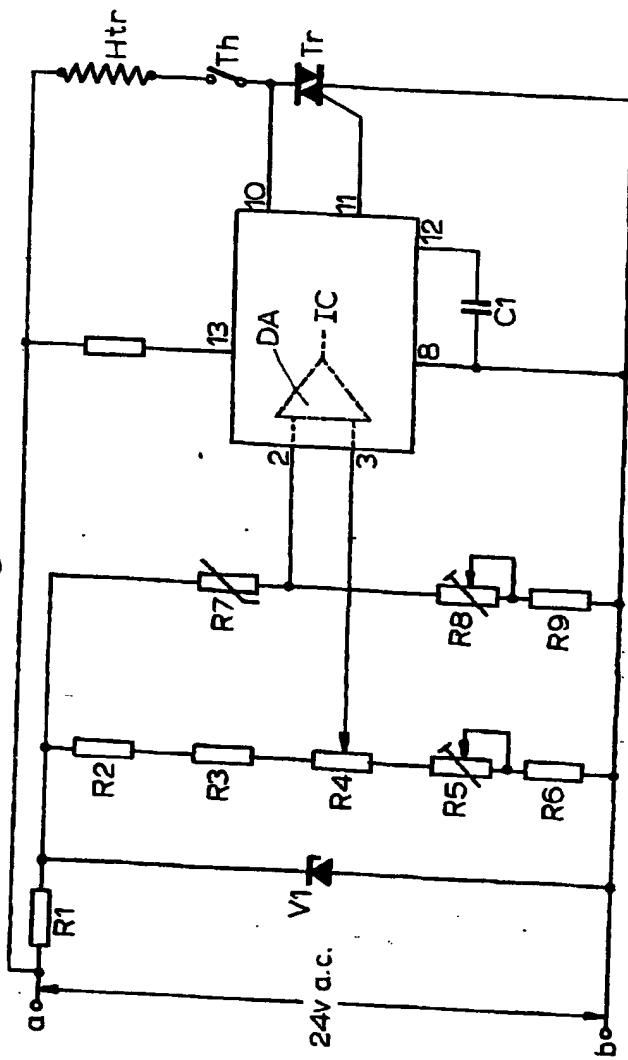
Sheet 1

Fig. 1.

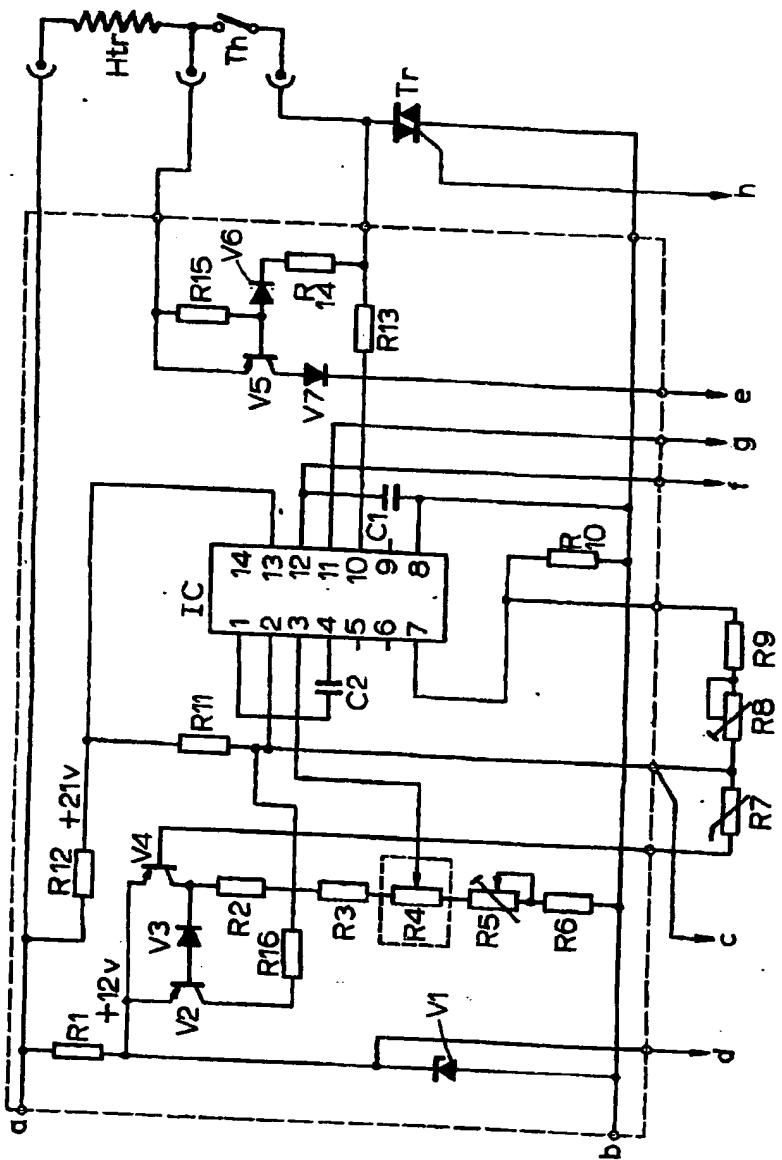


1294808 **COMPLETE SPECIFICATION**
4 SHEETS *This drawing is a reproduction of
the Original on a reduced scale
Sheet 2*

२०५



三
五
一
五



1294808

COMPLETE SPECIFICATION

4 SHEETS

This drawing is a reproduction of
the Original on a reduced scale

Sheet 4

